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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,916	07/11/2006	Michelle Leanne Styles	415852001100	1641
25225 7590 03/31/2010 MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			EXAMINER WILLIS, DOUGLAS M	
			ART UNIT 1624	PAPER NUMBER
			MAIL DATE 03/31/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,916	<b>Applicant(s)</b> STYLES ET AL.	
	<b>Examiner</b> DOUGLAS M. WILLIS	<b>Art Unit</b> 1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 January 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,6,7 and 9 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 6 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

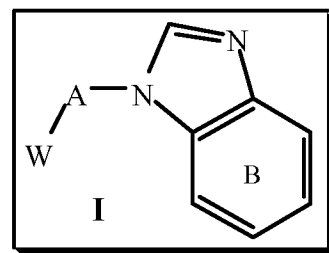
### *Status of the Claims*

A request for continued examination under 37 CFR 1,114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1,114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the *Final Rejection*, mailed on October 27, 2009, has been withdrawn pursuant to 37 CFR 1,114. Applicant's submission, filed on January 27, 2010, has been entered.

Claims 1-3, 6, 7 and 9 are pending in the current application. According to the *Amendments to the Claims*, filed January 27, 2010, claims 3 was amended and claims 4, 5, 8 and 10-13 were cancelled. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/AU2005/000022, filed January 12, 2005, which claims priority under 35 U.S.C. § 119(a-d) to AU 2004900103, filed January 12, 2004.

### *Status of Restrictions / Election of Species*

Applicant's affirmation of the following election, without traverse, in the reply filed on October 9, 2009, is acknowledged: a) Group I - claims 1-3 and 6, where A = -pyrazinyl, -pyrimidyl or -pyridyl; and Q = -a bond; and b) substituted benzimidazole of formula I - p. 40, example 20.



The requirement was made FINAL in the *Non-Final Rejection*, mailed on June 9, 2009.

Claims 7 and 9 were withdrawn from further consideration, pursuant to 37 CFR 1.142(b),

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as being drawn to a nonelected or cancelled invention, there being no allowable generic or linking claim.

The sections of U.S.C. Title 35 that formed the basis of prior rejections formulated, as well as any references supporting said rejections, that are not included with this Office action, may be found in either the *Non-Final Rejection*, mailed on June 9, 2009, or the *Final Rejection*, mailed on October 27, 2009. Furthermore, any rejections or objections of record not explicitly addressed herein below, are hereby withdrawn, in light of applicant's arguments and/or the *Amendments to the Claims*, filed January 27, 2010.

Thus, a third Office action and prosecution on the merits of claims 1-3 and 6 is contained within.

***Status of Claim Rejections - 35 U.S.C. § 103: Declaration Under 37 CFR 1.132***

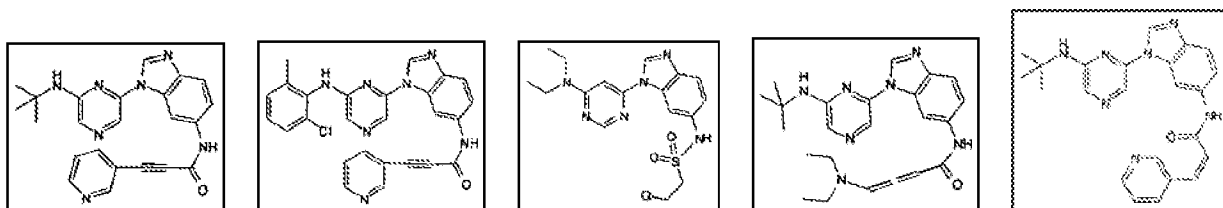
Applicant's arguments, on pages 9-13 of the *Remarks*, filed January 27, 2010, with respect to claims 4 and 5, have been fully considered, but will not be discussed further, since, according to the *Amendments to the Claims*, filed January 27, 2010, claims 4 and 5 have been cancelled by applicant.

The declaration under 37 CFR 1.132, filed January 27, 2010, is sufficient to overcome the rejection of claims 1, 2 and 6, made under 35 U.S.C. § 103(a) over Goulet, et al. in US 6,329,380.

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### ***New Claim Objections***

Claim 3 is objected to because of the following informalities: the following species, shown below, are not substituted benzimidazoles of the formula I and thus lack compliance with the *Requirement for Restriction / Election of Species*, mailed on April 13, 2009:



Appropriate correction is required.

### ***Claim Rejections - 35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2 and 6 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase *optionally substituted*, in claim 1, is a relative phrase which renders the claims indefinite. The phrase *optionally substituted* is not defined by the claims, the specification does not provide an adequate standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification, on pages 17-18, defines the phrase *substituted* using a boiler plate list of substituents, such as *halogen*, *C<sub>1-4</sub>alkyl*, *etc.*, and further discloses that the substituents themselves may be further *substituted*; however, the specification fails to explicitly limit the invention to any specifically

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disclosed embodiments. Consequently, the *substituted* benzimidazoles and compositions of the formula I have been rendered indefinite by the use of the phrase *optionally substituted*.

The examiner suggests removal of the phrase *optionally substituted* and providing discrete substituents for each occurrence where substituents are desired, to overcome this rejection.

### ***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

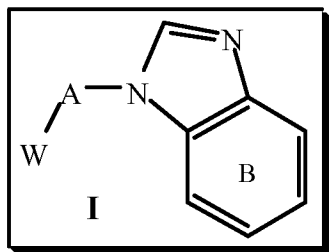
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

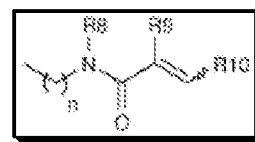
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2 and 6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Armstrong, et al. in US 6,498,165.

The instant application recites substituted benzimidazoles and compositions of the



formula I, shown to the left, where A = -pyrimidyl; W = -NR<sup>1</sup>R<sup>2</sup>, wherein R<sup>1</sup> = -H and R<sup>2</sup> = -C<sub>1-4</sub>alkylaryl; Y = - H and Z is shown to the right above, wherein n

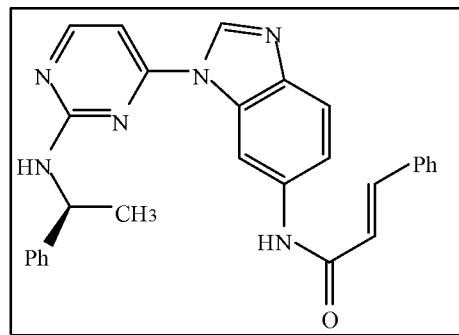
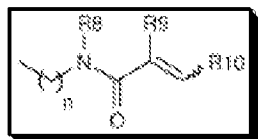


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= 0,  $R^8 = -H$ ,  $R^9 = -H$  and  $R^{10} = -H$ , as protein tyrosine kinase inhibitors.

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Armstrong, et al. (US 6,498,165) teaches substituted benzimidazoles and compositions, shown to the right, where A = -pyrimid-4-yl; W = -NR<sup>1</sup>R<sup>2</sup>, wherein R<sup>1</sup> = -H and R<sup>2</sup> = -1-phenethyl; Y = -H and Z is shown to the left, wherein n = 0, R<sup>8</sup> = -H, R<sup>9</sup> = -H and R<sup>10</sup> = -Ph, as protein tyrosine kinase inhibitors [column 145, example 152; and pharmaceutical compositions - column 24, lines 26-38]. Moreover, in the genus disclosure, Armstrong teaches that R<sup>10</sup> may alternatively be hydrogen [column 6, line 2 - R<sup>6</sup>/R<sup>6a</sup> = -NHC(=O)R<sup>11</sup>, wherein R<sup>11</sup> = -C<sub>2</sub>-C<sub>6</sub>alkenyl (unsubstituted) - column 7, lines 53-55].



The only difference between the instantly recited substituted benzimidazoles and compositions of the formula I and Armstrong's substituted benzimidazoles and compositions is R<sup>10</sup> is hydrogen in the instantly recited substituted benzimidazoles and compositions of the formula I, whereas R<sup>10</sup> is phenyl in Armstrong's substituted benzimidazoles and compositions.

In the chemical arts, it is widely accepted that *structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions or compounds, creates a prima facie case of obviousness.* {See *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, No. 06-1329, slip op. at 9 (Fed. Cir. June 28, 2007) (quoting *In re Dillon*, 919 F.2d 688, 692 [16 USPQ2d 1897] (Fed. Cir. 1990) (en banc)); and *In re Papesch*, 315 F.2d 381 [137 USPQ 43] (C.C.P.A. 1963)}.

Consequently, since: a) Armstrong teaches substituted benzimidazoles and compositions, where R<sup>10</sup> is phenyl; b) Armstrong teaches substituted benzimidazoles and compositions, where



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hydrogen and phenyl are alternatively usable at  $R^{10}$ ; and c) the courts have recognized that *structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions or compounds, creates a prima facie case of obviousness*, one having ordinary skill in the art, at the time this invention was made, would have been motivated to utilize the teachings of Armstrong and replace the phenyl at  $R^{10}$  in Armstrong's substituted benzimidazoles and compositions, with an alternatively usable hydrogen, with a reasonable expectation of success and similar therapeutic activity, rendering claims 1, 2 and 6 obvious.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

#### ***Allowable Subject Matter***

No claims are allowed.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOUGLAS M. WILLIS, whose telephone number is 571-270-5757. The examiner can normally be reached on Monday thru Thursday from 8:00-6:00 EST.

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The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DOUGLAS M WILLIS/  
Examiner, Art Unit 1624

**/James O. Wilson/  
Supervisory Patent Examiner, AU 1624**